Syfovre™ (pegcetacoplan) – New drug approval

- On February 17, 2023, Apellis announced the FDA approval of Syfovre (pegcetacoplan) intravitreal injection, for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

- GA is an advanced form of AMD caused by the growth of lesions, which destroy the retinal cells responsible for vision. GA affects about 1 million people in the U.S., and it is one of the leading causes of blindness.

- Syfovre, a compliment inhibitor, is the first approved therapy for GA. By targeting C3, Syfovre is designed to provide control of the complement cascade, part of the body's immune system.

- The efficacy of Syfovre was established in two randomized, sham-controlled studies (OAKS and DERBY) in 1,258 patients with GA, with or without subfoveal involvement, secondary to AMD. Patients were randomized to Syfovre monthly or every other month, or sham administered monthly or every other month. The primary endpoint was the mean rate of GA lesion growth.

    - In the two studies, both monthly and every other month Syfovre reduced the rate of GA lesion growth through 24 months compared to sham.

Study	Group	Rate of GA lesion area growth (mm^2) Baseline to month 24		
		Slope (SE)	Difference (95% CI) in Slope from Sham Pooled	Percent Difference from Sham Pooled
OAKS	Syfovre monthly	3.11 (0.148)	−0.87 (−1.27 to −0.47)	−21.9%
	Syfovre every other month	3.26 (0.134)	−0.72 (−1.10 to −0.33)	−18.1%
	Sham pooled	3.98 (0.143)	N/A	
DERBY	Syfovre monthly	3.28 (0.125)	−0.73 (−1.14 to −0.31)	−18.1%
	Syfovre every other month	3.31 (0.129)	−0.70 (−1.11 to −0.28)	−17.4%
	Sham pooled	4.00 (0.169)	NA	

- Syfovre is contraindicated in patients with:

    - Ocular or periocular infections
    - Active intraocular inflammation

- Warnings and precautions for Syfovre include endophthalmitis and retinal detachments, neovascular AMD, intraocular inflammation, and increased intraocular pressure.

- The most common adverse reactions (≥ 5%) with Syfovre use were ocular discomfort, neovascular AMD, vitreous floaters, and conjunctival hemorrhage.

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- The recommended dose for Syfovre is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.
    - Syfovre must be administered by a qualified physician.
- Apellis plans to launch Syfovre by the beginning of March. Syfovre will be available as a 150 mg/mL single-dose vial.

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